Blood Bank
of San Bernardino
and Riverside Counties

September 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98N-0673
21 CFR Parts 606 and 640
Final Rule
Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma

To Whom It May Concern:

This revision to the CFR is appropriate and necessary. I have only one concern, and that relates to 640.34 (b). The regulation reads, "The plasma shall be separated from the red blood cells, frozen solid within the timeframe specified in the directions for use for the specific device, and stored at –18°C or colder." The requirement that the plasma be frozen *solid* within the timeframe specified is not consistent with the FDA memorandum of November 13, 1989 entitled, "Eight-Hour Hold." This memorandum stated that "data submitted support that plasma is suitable for the manufacture of Platelets, Fresh Frozen Plasma, Cryoprecipitated AHF and Recovered Plasma" after an eight-hour hold at room temperature. It is substantially different to require that plasma be frozen solid in eight hours vs. placed in the freezer at eight hours.

Many blood centers collect plasma at remote collection sites and are reliant on the ability to hold plasma at room temperature for eight hours in the approved containers. Our production of Fresh Frozen Plasma and Cryoprecipitate depends heavily on the ability to collect at remote sites. Therefore, we do NOT want this eight-hour room temperature hold rule to change. It would seem if the data to support this process were adequate in 1989, they should still be adequate. Please do not change the requirement.

Sincerely,

Pat Distler

Pat Distler, MS, MT(ASCP)SBB
Vice President, Operations

PD:lmr\7206

98N-0673

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384 Orange Show Road, P.O. Box 5729, San Bernardino, CA 92412-5729 • Tel: 909-885-6503 • Fax: 909-381-2036

ADMINISTRATION

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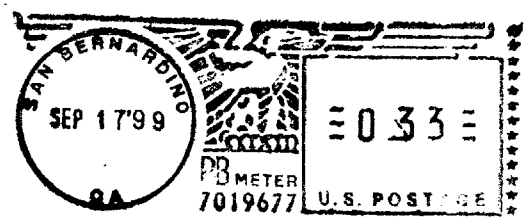
384 Orange Show Road
P.O. Box 5729
San Bernardino, CA 92412-5729



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